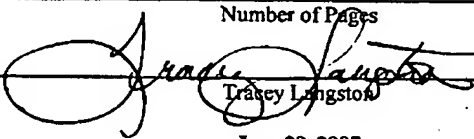


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In re United States Patent Application of:)	Docket No.:	4121-177
Applicants:)	Conf. No.:	2987
Application No.:)	Art Unit:	1633
Date Filed:)	Examiner:	Kevin Kai Hill
Title:)	Customer No.:	23448
INACTIVE TRANSCRIPTION FACTOR TIF-1A AND USES THEREOF)		

FACSIMILE TRANSMISSION CERTIFICATE**ATTN: Examiner Kevin Kai Hill****Fax No. (571) 273-8300**

I hereby certify that this document is being filed in the United States Patent and Trademark Office, via facsimile transmission, addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, and transmitted on the date specified below, to United States Patent and Trademark Office facsimile transmission number (571) 273-8300.

7
Number of Pages

Tracey Longston
June 29, 2007
Date

**RESPONSE TO MAY 31, 2007 RESTRICTION REQUIREMENT IN U.S. PATENT
APPLICATION NO. 10/539,473**

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Sir:

This responds to the May 31, 2007 Office Action in the above-identified application.

4121-177

The time for responding to the May 31, 2007 Office Action without extension was set at one month, or June 30, 2007. This response is therefore timely.

In the May 31, 2007 Office Action, the Examiner has required restriction under the provisions of 35 U.S.C. § 121 among:

- Group I: Claims 1-10, 17 and 20, drawn to a pharmaceutical composition comprising a nucleic acid molecule encoding an inactive form of the human transcription initiation factor TIF-1A, and host cells comprising said nucleic acid molecule;
- Group II: Claims 22-23, drawn to a method for treatment of a disease which is associated with an increased cell proliferation, the method comprising administering to a subject in need of treatment a nucleic acid molecule encoding an inactive form of the human transcription initiation factor TIF-1A;
- Group III: Claims 11-15, drawn to a recombinant host cell comprising a nucleic acid molecule encoding an inactive form of the human transcription initiation factor TIF-1A, wherein the serine residue at position 633 and/or 649 is replaced by another amino acid residue, a method of producing said TIF-1A comprising culturing said recombinant host cell, and an inactive form of the human transcription initiation factor TIF-1A produced by said method;
- Group IV: Claims 16 and 18-19, drawn to a transgenic animal comprising a nucleic acid molecule encoding an inactive form of the human transcription initiation factor TIF-1A; and
- Group V: Claim 21, drawn to a method for identifying compounds capable of inhibiting the conversion of an inactive pre-form of TIF-1A into a biologically active form.

Applicants hereby elect **WITH TRAVERSE**, Group I, claims 1-10, 17 and 20 of the present application, directed to a pharmaceutical composition. No class or subclass categorizations are provided.

4121-177

Traversal of Restriction

In order for a Restriction Requirement to be made, there must be independent or distinct inventions, which would provide a serious burden on the examiner if restriction is not required.

It is noted that the International Examining Authority in priority application PCT/EP03/14016 acknowledged that the claims of Groups I-IV related to a single inventive concept. In particular, the International Preliminary Examination Report, dated March 17, 2005 states that producing an inactive TIF-IA factor lacking posttranslational modifications was not obvious in the view of the prior art. Thus, the subject matter of Groups I-IV are unified by their common special technical feature of a nucleic acid molecule encoding an inactive form of TIF-IA, wherein TIF-IA is not, or is not completely, posttranslationally modified, which has been acknowledged by the examiner. (Office Action mailed May 31, 2007, page 3, 3rd para., lines 6-7.)

The subject matter of Groups I, III and IV is technically interrelated in that the host cells of Group III and the transgenic animal of Group IV encompass the nucleic acid of Group I. Further, the method of treatment of Group II relates to the use of the product of Group I. Hence, the subject matter of Groups I-IV encompass the same essential feature and, therefore, relate to the same invention, *i.e.* an inactive TIF-IA factor lacking posttranslational modifications, which can be searched and examined without a burden. Therefore, examination of the claims of Groups I-IV together is requested.

Species Election

Upon election of Group I, the examiner has required a species election of alleged species within the claims of Group I. Specifically, the examiner identifies the following alleged patentably distinct species:

- (i) a TIF-IA mutation species, as recited in claims 2-7,
- (ii) a cell type species, as recited in claim 12,
- (iii) a recombinant vector species as described in the specification and claims 8-9, and
- (iv) a cell line type species as described in the specification and claim 17.

4121-177

The requirement for a species election is traversed. As set forth in MPEP §803, a proper restriction requirement is made when the inventions are independent (MPEP §§ 802.01, 806.04, 808.01) or distinct as claimed (MPEP §§ 806.05-806.05(i)); and there is a serious burden on the Examiner if restriction is not required (MPEP §§ 803.02, 806.04(a)-(i), 808.01(a) and 808.02). However, even if the species are viewed as independent or distinct, but the claimed subject matter in each group is related by a "commonality of operation, function and effect" (MPEP § 806.04(e)), then requiring election of a single species is improper.

Additionally, MPEP § 803 states that "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."

It is submitted that the four categories of species identified in the Requirement for Election mailed May 31, 2007 each include species that possess a commonality of design, operation or effect and therefore relate to a single general inventive concept.

Specifically, the species of the group identified as TIF-IA mutation species are: amino acid substitution of the serine residue at position 633 and/or position 649 (claim 2), amino acid substitution of the serine residue at position 649 with alanine (claim 3), amino acid substitution of at least one amino acid residue being part of the recognition motif for a phosphatase or kinase comprising the serine residue at position 643 and/or 649 (claim 4), amino acid substitution of the serine residue at position 44 and/or 199 (claim 5), amino acid substitution of the serine residue at position 44 with alanine or aspartic acid and/or amino acid substitution of the serine residue at position 199 (claim 6), and amino acid substitution of at least one amino acid residue being part of the recognition motif for a phosphatase or kinase comprising the serine residue at position 44 and/or 199 (claim 7). As all of these mutations are amino acid substitutions, they satisfy the criterion of "commonality of design, operation or effect."

All species of the group of cell type species including: mammalian cell, bacterial cell, insect cell or yeast cell are host cells for administration of the recombinant vector of claim 8. All of these cell types must be an adequate host for the vector, providing an adequate environment in which the vector can reproduce itself. As such, these host cells are linked by a "commonality of design, operation or effect."

4121-177

The third and fourth species are identified by their description in the specification, but no list of those species is present in the claims. Claims 8-9 recite "a recombinant vector" comprising the nucleic acid molecule of claim 2. As such, all vectors encompassed by the claim possess "commonality of design, operation or effect." The examiner, however, has required election of a particular species of vector "suitable for use," as described in the specification, at page 17, lines 14-22. Applicants respectfully submit that such an election is not necessary.

Similarly, claim 17 recites a cell line comprising at least one nucleic acid molecule of any one of claims 1 to 7. As such, all vectors encompassed by the claim possess "commonality of design, operation or effect." The examiner, however, has required election of a particular species of cell line type as described in the specification, at page 17, lines 20-26 and paragraph bridging pages 17-18. Applicants respectfully submit that such an election is not necessary.

In order that this response fairly meets the substance of the Office Action in all respects, even though the election requirement is traversed by Applicants, a single disclosed species of each identified group is elected by applicants, with traverse: i) S649 as the TIF-IA mutation species, ii) mammalian cells as the cell type species, iii) virus as the species of the recombinant vector, and iv) mammalian cells as the cell line type.

It is acknowledged by applicants that in a species election, if any species is found to be allowable, then an additional species will be examined, until all species have been examined. *i.e.* all TIF-IA mutation species, all cell type species, all species of the recombinant vector, and all cell line types. If any generic claim is finally held to be allowable, all claims drawn to species containing all elements of the generic claim will also generally be held to be allowable. (MPEP § 806.04(d))

Accordingly, it is respectfully requested that the species set forth in claims 1-10, 17 and 20 be retained in the aggregate for examination or, alternatively, that an additional explanation in support of a species election requirement be provided.

Rejoinder

In the event that the restriction requirement between the composition (Group I) and method (Group II) aspects of the invention is made final, Applicants responsively request rejoinder of